

**NEUROLOGICAL DEVICES PANEL**  
of the  
**MEDICAL DEVICES ADVISORY COMMITTEE**

*Eighteenth Meeting*  
**Hilton Washington D.C. North**  
**620 Perry Parkway**  
**Gaithersburg, Maryland**  
**November 30, 2004**

**Panel Chairperson**  
Kyra J. Becker, M.D.

**Executive Secretary**  
Janet L. Scudiero, M.S.

**Confluent Surgical, Inc., DuraSeal Dura Sealant System, P040034**

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|--------------|-----------|---|
| <b>8:45</b>  | <b>am</b> | <b>Call to Order</b><br><b>Conflict of Interest and Deputization to Voting Member Status Statements</b><br><b>Panel Introductions</b><br><b>Update since the June 15, 2004 Meeting</b><br>Stephen Rhodes, Chief, Plastic and Reconstructive Surgery Devices Branch (PRSB)   |
| <b>9:00</b>  | <b>am</b> | <b>1<sup>st</sup> Open Public Hearing*</b>  |
| <b>9:30</b>  | <b>am</b> | <b>Sponsor Presentation</b><br>Eric P. Ankerud, J.D., Vice President, Clinical, Regulatory and Quality,<br>Confluent Surgical, Waltham, MA<br>Patrick Campbell, Ph.D. Vice President, Research and Development<br>Confluent Surgical, Waltham, MA<br>John M. Tew, Jr., M.D., Mayfield Clinic and Professor, Department of Neurosurgery,<br>University of Cincinnati<br>G. Rees Cosgrove, M.D., F.R.C.S. (C.), Associate Professor, Neurosurgery,<br>Harvard Medical School, Massachusetts General Hospital, Boston, MA<br>Harry van Loveren, M.D., Tampa General Hospital and Professor and Chairman,<br>Director<br>of Skull Base and Cerebrovascular Surgery, University of South Florida |
| <b>10:30</b> | <b>am</b> | <b>Break</b>  |
| <b>10:45</b> | <b>am</b> | <b>FDA Presentation</b><br>Peter L. Hudson, Ph.D.<br>Michael J. Schlosser, M.D.   |
| <b>11:30</b> | <b>pm</b> | <b>Lunch</b>  |
| <b>12:30</b> | <b>pm</b> | <b>Panel Deliberations and FDA Questions</b><br>Alexa I. Canady, M.D.<br>David T. MacLaughlin, Ph.D.  |
| <b>2:30</b>  | <b>pm</b> | <b>2<sup>nd</sup> Open Public Hearing*</b>  |
| <b>3:00</b>  | <b>pm</b> | <b>Break</b>  |
| <b>3:15</b>  | <b>pm</b> | <b>FDA and Sponsor Summations, up to 15 minutes each</b>  |
| <b>3:45</b>  | <b>pm</b> | <b>Panel Vote</b>   |

**5:00 pm Adjournment**

\* **Open Public Hearings** – Interested persons may present data, information, or views, orally or in writing, on the meeting agenda. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.